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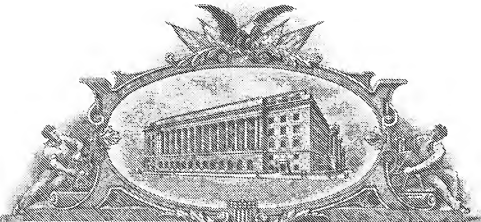

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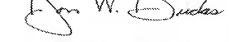

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)		
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Additional inventors are being named on the additional *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

DISEASE MANAGEMENT SYSTEM

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☑ Customer Number: 31,278

OR

☐ Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country		Telephone		Fax	

ENCLOSED APPLICATION PARTS *(check all that apply)*

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☑ Applicant claims small entity status. See 37 CFR 1.27.

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Respectfully submitted,

SIGNATURE

Date 1/16/04

REGISTRATION NO. 34.792 *(if appropriate)*

Docket Number: 14715-0000

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DISEASE MANAGEMENT SYSTEM

FIELD OF THE INVENTION

[0001] The present invention relates to a comprehensive patent management system. Specifically, the present invention provides advanced diagnostic, prognostic and therapeutic capabilities to healthcare workers located in remote, rural and underdeveloped urban centers. More specifically, the present invention provides non-physician healthcare workers access to advanced diagnostic, prognostic and therapeutic capabilities useful for managing patients with chronic diseases, such as human immunodeficiency virus (HIV) infected persons.

BACKGROUND OF THE INVENTION

[0002] Human immunodeficiency virus ("HIV") was first identified in 1981, and has since spread in epidemic proportions throughout the world. In the early years, the diagnosis of AIDS was an automatic death sentence, and the scientific community embarked on an aggressive search for a vaccine and a cure.

[0003] While these goals are still elusive, treatments have been devised that have resulted in HIV/AIDS becoming a treatable, chronic disease. Anti-viral drugs are taken in various combinations and according to a range of schedules, for the remainder of the patients' lives. This regime is called High Activity Anti-retroviral Therapies (HAART). The ideal result is a lowering of the virus in the bloodstream to undetectable amounts. In this case, the patients' immune systems recover, or do not deteriorate, and they can live healthy and productive lives. This scenario is a reality for most in the USA, Canada and Europe. These developed countries have the political will to deal with this disease, and a complex medical infrastructure to diagnose and treat their population. The public health message of prevention is also emphasized. In addition, from a public health standpoint, it is hypothesized that lowering many individual's viral load

effectively lowers the viral load of the entire community, and may slow transmission.

[0004] In stark contrast, many developing countries across Africa, Asia and South America have unsophisticated medical infrastructure. We use South Africa as an example. South Africa holds the dubious distinction of having the highest AIDS infection rate/death rate in the world, with other southern African nations in close contention. In late 2003, the South African Government released a plan to roll out HAART as part of an HIV/AIDS management plan.

[0005] South Africa has become a tragic laboratory for how devastating the AIDS epidemic can become when left unchecked. In this area of Africa, HIV is primarily transmitted through unprotected heterosexual sex. It can take many years for a person infected with HIV to become ill. During this period, sexually active adults spread the virus through the population; HIV is also transmitted from mother to baby. Once a patient's immune system begins to deteriorate to full-blown AIDS, they easily contract opportunistic infections like tuberculosis, pneumonia and cancer. A significant proportion of the South African Department of Health ("DOH") budget of US$3 billion is currently spent on treating these secondary diseases with costly hospitalization and medication.

[0006] Without the rollout of an HIV/AIDS management plan which includes universal access to HAART, by 2008 the current life expectancy for a South African male will fall from 54 to 36 years, and the estimated number of AIDS orphans will rise from 420 thousand to 1.6 million. The social cost is a catastrophe of grave proportion; the indirect economic cost will be a devastating 17% (US$ 22 billion) of the GNP.

[0007] The health care budget of the DOH currently spent on treating the opportunistic diseases and end-stage infection could more effectively be focused on providing HAART to the infected population as an integral part of a comprehensive management plan,. The factors that prevented aggressive

HAART treatment of the infected population in South Africa in the past are complex. Recent legal developments have obliged the DOH to administer the anti-viral Nevirapine to pregnant mothers and their newborn babies, and settlement has been reached regarding patents of many of the anti-viral drugs. Even as the political will has evolved toward an aggressive management plan, there is limited infrastructure to administer HAART to the urban population, even less so to those dispersed in remote rural areas.

SUMMARY OF THE INVENTION

[0008] The present invention provides advanced diagnostic, prognostic and therapeutic capabilities to healthcare workers located in remote, rural and underdeveloped urban centers. More specifically, the present invention provides non-physician healthcare workers access to advanced diagnostic, prognostic and therapeutic capabilities useful for managing human immunodeficiency virus (HIV) infected persons. The present invention is a practical solution to managing HIV infection in remote undeveloped population centers by providing individualized patient care without having highly trained infectious disease physician specialists located at each site.

[0009] Human immunodeficiency virus infection presents as a complex multi-factorial disease that is challenging to manage even in modern urban centers where state-of-the-art teaching hospitals and highly trained physician specialists are readily available. Patient management becomes considerably more difficult when infected individuals are located in underdeveloped urban centers and remote rural locations (herein after referred to as remote patient management). Remote patient management is further exacerbated when the most highly trained healthcare provider is a nurse or Red Cross-Red Crescent aid-worker.

[0010] In most, if not all, remote patient management environments laboratory facilities, pharmacies and diagnostic imaging facilities are located hundreds of miles away. Moreover, even when these facilities are located within

a reasonable proximity, patient transportation to and from testing and drug dispensing centers may be unavailable or at best unreliable.

[0011] Persons infected with HIV require regular diagnostic work-ups in order to monitor disease progression and therapy efficacy. Moreover, test interpretation and therapeutic recommendations require the expertise of a trained infectious disease specialist. Consequently, persons located in remote patient management environments are less likely to be tested for HIV disease because they have learned form experience that treatment options are simply not available. Therefore, it does them no good to know their immune status. As a result a culture of fear and ignorance has proliferated in underdeveloped urban centers and remote rural locations that feed an every growing HIV pandemic.

[0012] The present invention provides a solution to this problem. Recent telecommunication advances have made modem access to centralized computer databases available even in the most remote and desolate areas. The present invention utilizes this global communication phenomena to bring cutting edge patient management tools directly to the patient. Briefly, in one embodiment of the present invention a non-physician healthcare worker is provided with questionnaires and protocols developed by HIV physician experts. Using these tools combined with rudimentary physical examination skills the non-physician healthcare provider becomes a virtual infectious disease diagnostician. Answers to the patient questionnaire and the results of the physical examination are entered into the database and the algorithm feature of the present invention collates and analyzes the individualized patient data. Appropriate biological samples are collected, principally blood, which are sent to an urban testing facility where the samples are tested and the results are entered into the same database and the algorithm of the present invention applied. Based on the combined results of the laboratory tests, questionnaire and physical examination a preliminary diagnosis is established. Persons presenting consistent with HIV-related issues can then be further examined and additional tests run as indicated.

[0013] The computer database of the present invention, which is updated regularly with state-of-the-art diagnostic protocols and therapeutic regimens, directs the non-physician's selection of diagnostic tests and instructs them as to what physical examinations to conduct. This information is again entered into the database of the present invention and the algorithm applied. After the data is collated the non-physician health care worker is provided with an individualized therapeutic regimen for the patient. Required medications are sent to the remote rural or urban site and administered to the patient consistent with the recommendations provided by the present invention's algorithm. Patients then return regularly for follow-up.

[0014] Each time the patient is examined and tested the resulting data is collated, entered and analyzed by the algorithm of the present invention. The non-physician healthcare worker is then provided with an individualized prognostic determination and recommended changes to the therapeutic regimen if required. Consequently, persons in undeveloped urban centers and remote rural settings will now have access to modern diagnostic, prognostic and therapeutic capabilities similar to those available to citizens of the countries with sophisticated health care systems. Using the system of the present invention, the cycle of ignorance, fear and denial that feeds the HIV pandemic can be broken and truly advanced remote patient management becomes available to those most in need thereof.

[0015] Thus, the system of the present invention offers an elegant and practical solution which will allow, as an example, wide and cost-effective HAART therapy in the developing world. In an illustrative embodiment, the South African DOH will be offered a complete HAART management system that includes transport of blood samples to laboratories, input of data, drug prescription generation and dispensing, as well as psychosocial and nutrition support and education.

[0016] One of the features of this novel system is a computer-based algorithm that receives input of blood viral loads, CD4 cell levels (a measure of immune function) and other critical Patient information and recommends the most medically effective drug regimen, as approved by the provider.

[0017] Laboratory services, data input, drug packaging and drug dispensing currently exist in South Africa, but not as part of an integrated system. The importance of offering the DOH an integrated management package cannot be overemphasized. In addition, the collection of data that this system facilitates is invaluable for financial, demographic and scientific projections.

[0018] In developed countries, even though sophisticated medical infrastructures already exist, there are limitations to their efficiencies. Managed care organizations, for example, as well as publicly-funded health systems, will all benefit from the cost-control, data collection and the comprehensive, current, state-of-the-art HIV/AIDS management plan offered by the present invention.

OBJECTIVES

[0019] In an illustrative embodiment, the present invention includes a specialized algorithm to assist health care workers with the medication management of HIV/AIDS and related opportunistic infections such as tuberculosis (TB). Some of the major objectives include:

- Medication protocols for specific/individual patients based on evidence-based treatment algorithms
- Seamless, rapid implementation of new drug protocols
- Support and tracking of drug reaction mitigation
- Tracking of drug resistant viral mutations

- Treatment regardless of geographic location and distance from urban centers
- Automatic monitoring of high-risk patients
- Complex cases referred for Medical Specialist consultation
- Reliable geographic health statistics for public and private sector health planners

[0020] Among the benefits which may be obtained by this system are that public and private healthcare service providers will be enabled to implement and operate a cost-effective system to diagnose and treat patients with HIV/AIDS and related diseases. This will hold true even within limitations of poor medical infrastructure. This system does not require significant increase in the number of doctors needed to treat this disease and can coexist with many of the present treatment systems. Such a system will effectively result in a reduction in opportunistic infection rates, as well as lower overall usage of medical services by patients. The algorithm will be an effective tool to ensure accurate and cost effective treatment of HIV/AIDS patients. Medically, the resultant compliance with and monitoring of treatment regimes helps prevent drug resistance, which requires more expensive treatment.

[0021] The value of the data collection function of the present invention for disease management and planning of future needs cannot be underestimated. The centralized data collection also facilitates outcome evaluation and pharmaceutical inventory control, and efficient use of the healthcare dollar.

[0022] In an illustrative embodiment, the system of the present invention will provide the medical community and governmental agencies, in both the public and private healthcare sectors, with a comprehensive and flexible management plan for HIV/AIDS. At the core of the plan is an interactive system that uses algorithms to direct health care workers in the medication management of

HIV/AIDS. The complete plan will allow providers to implement and operate a high quality, cost effective system to diagnose and treat patients with HIV/AIDS and related diseases while gathering invaluable data. The system is effective even within the limitations of poor medical infrastructure. The system has the ability to supply the tools for meaningful change in social and medical policy in the developing world, as well as to enhance care in the developed world.

[0023] The system of the present invention offers a complete integrated healthcare solution. The system will be able to integrate laboratory services and medication dispensing in countries that cannot currently deliver comprehensive integrated care for HIV/AIDS due to poor or inefficient healthcare infrastructure. Offering only a single component is not a valuable solution to these countries.

[0024] In an illustrative embodiment, the system will be able to take advantage of the South African Government's recent policy statement recommending HAART as part of the comprehensive treatment of HIV/AIDS. The system of the present invention can be implemented as a collaborative effort to provide high quality cost-effective healthcare in a timely manner, in accordance with the South African DOH's HAART strategy.

TECHNOLOGY INFRASTRUCTURE

[0025] In an illustrative embodiment, the technology resides outside of developing countries, and is hosted in a "round the clock" facility to allow for time-zone variances. Algorithm rule sets are designed and implemented to be culture, country-specific and regional-specific, and easily enhanced to the most current scientific and medical knowledge as agreed to by the provider.

[0026] In an illustrative embodiment, the system includes a multi-tiered fully redundant highly available architecture. The system will be able to accept input from a variety of existing sources, such as client computers running the various Windows, Unix or Linux desktop operating systems, laboratory based computer

systems, voice interactive systems and other potential devices including cell phones or specialized medical diagnostic devices. Various communication protocols including TCP/IP will be used to communicate to the servers. The servers may be based locally and/or remotely and will also run in a fully redundant and recoverable manner using current standard computing standards. The Servers will utilize database systems from either Oracle or Microsoft SQL or IBM. DB II. A variety of programming tools, languages and interfaces will be used to implement the solution including but not limiting to C#, C++, Visual Basic, HTML, XML, SSL, Data Base queries, Visio and add on packages are used in development of the system.

[0027] A proprietary source code is utilized. The multi-tiered architecture and database design implements a security architecture to provide safeguards to protect the algorithms and patient information form being accessed in a malicious or unauthorized manner. All transactions will be logged and tracked. Communications will be encrypted using the latest standards including 48 bit SSL or 128 bit where possible.

[0028] The database servers and application servers, will be placed behind a firewall and use industry accepted standards to protect against unauthorized access.

[0029] The system algorithm is built upon a state-of-the-art medical knowledge base. The most current peer-reviewed treatment protocols will be available. The system supports customizations from end-users and local healthcare personnel to ensure that local requirements are taken into account.

[0030] The system includes a focus on communication and prevention options that are integrated with the algorithm implementation. One benefit, for example, will be the demystification of HIV/AIDS amongst the general public as well as patients. The system is capable of integrating input from existing local

grass-roots healthcare workers which will enhance enrolment levels as well as compliance levels.

[0031] One of the benefits of the system is a minimal reliance on data management and control by rural healthcare workers. In an illustrative embodiment, the pathology service provider will enter data into the system. Modem access to centralized computer databases can be achieved, for example, via cell phone. In the alternative, laptops, desktops, or hand held devices with modem access via land line or satellite link or other telecommunication means known to those of skill in the art can be utilized. The medical algorithm will constantly be evaluated and updated to be current with the most recent clinical recommendations. The system will consider and incorporate international state-of-the art treatments, and take into account specific local conditions.

[0032] The system also has the capability to work within, and with respect to, the existing culture and traditional society. Input from local leaders and healthcare workers can be incorporated to maximize local acceptance and compliance.

DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT OF THE INVENTION

[0033] A flow chart of an illustrative embodiment of the operating system loop of the present invention is depicted in Figure 1.

[0034] One of the purposes of the system of the present invention is to allow low-level healthcare workers in developing countries to provide in a cost-effective manner patient diagnostics, ongoing treatment, and outcomes evaluation at a level similar to that provided by an HIV/AIDS specialist physician.

BENEFITS OF THE SYSTEM

[0035] Developing countries are resource poor in their medical infrastructure and thus have a low number of medical personnel. South Africa, as an example,

has a limited number of doctors in general, and infectious disease specialists in particular, as well as nurses and other primary health care workers. This is true in both the rural and urban settings, even within larger tertiary hospitals. In rural primary healthcare clinics the highest qualified healthcare worker is typically a nurse. The innovation of the present invention will enable the resource-poor settings to act as if an HIV/AIDS specialist were present.

[0036] The present invention will dramatically improve the efficiency of the primary health care system to deliver care to its constituency, both in the urban areas, and to the large percentage of the population that live in rural conditions. The primary health care nurses, with the innovative support of the system, can more efficiently provide care for a larger number of patients, and only those who fall outside of the parameters of the algorithm will need to be referred to hospitals or medical specialists.

[0037] The challenge of compliance with complex anti-retroviral regimens is faced in both developing and developed countries, and is enhanced in uneducated populations. This lack of compliance in HIV/AIDS is particularly dangerous due to the resultant development of resistant HIV, as well as opportunistic diseases associated with AIDS. This system is innovative in its approach to increased compliance by enhancing systematic feedback and automated recordkeeping. In addition to the clinical education provided directly to the patient, the system will note deviations in patterns that indicate low compliance, either through altered immune response, or missed appointments. Communicating this information to the local health care worker will facilitate intervention and increased compliance. Positive reinforcement and support of the front-line worker is an additional component.

[0038] The system of the present invention allows all personnel and patients to benefit from advances in the science of HIV/AIDS. This is a rapidly evolving field, with advances in all areas, from pharmaceuticals to education interventions,

being published on an ongoing basis. As these changes are vetted by, for example, a medical advisory board, and approved by the governmental authorities, they can be implemented almost immediately in the remotest rural location by altering criteria in the central algorithm. One aspect of the novelty of the invention lies in the flexibility inherent in its design to deal with the rapidly evolving science.

[0039] On the level of the individual patients, the system will enable a rapid response to their changing treatment needs, such as in the development of resistance, or toxicity from the antiretroviral drugs.

[0040] HIV-positive patients, who are medically eligible for antiretroviral therapy but do not receive it, are highly susceptible to life-threatening opportunistic infections. These are very expensive to treat with costly hospitalization. The innovative efficiency of the system of the present invention will allow resource poor countries to institute widespread HAART, which has been shown to keep patients healthy, productive and out of hospital for significant periods of time. The system will thus provide remarkable cost-saving to both the health system and society at large. The system will also be able to cope with multiple disease conditions prevalent in developing countries, in particular HIV/AIDS in combination with tuberculosis and malaria. The system will optimize resources and minimize costs in providing treatment to patients suffering any combination of these diseases. Furthermore, as the science evolves, some have hypothesized that patients that are well cared for and monitored may be able to reduce their drug intake for periods of up to one year resulting in significant cost savings compared to conventional treatment regimes.

[0041] The increased compliance that the system facilitates can reduce the number of patients who become resistant to first line therapy and who need to progress to more expensive, and less effective, alternate regimens.

[0042] The system provides for enhanced data collection and utilization. The tracking capability of the system will create a valuable statistical database. It will have a complete record of each individual's HIV treatment, as well as tracking for each clinic, geographical area, drug performance, toxicity, and every other variable within the system. This data can be utilized for budgetary extrapolations, as well as identifying trends in the disease and its management. An additional use is in the trials for new technology and pharmaceuticals. Research on a small sample can be projected onto the existing system. The data on individual clinics and regions can be used for quality control, and to assess the necessity for re-allocation of financial, staffing or training resources.

OPERATING SYSTEM LOOP

[0043] An illustrative example of an algorithm that may be utilized with the system is depicted in Figures 2.1 and 2.2. (Note that Figure 2.1 and Figure 2.2 are part of the same flow chart. The arrow at the top of Figure 2.2 is a continuation of the arrow at the bottom of Figure 2.1).

[0044] The operating system loop works as described in Figure 1.

1. Patient interface. An initial visit includes a patient history, a physical examination, and an HIV test. The patient has a return visit to receive an HIV test result. Recheck visits are performed per the protocol and treatment plan. The nurse will SMS the call center with the requirements for pick-up of lab sample, or use other technology as appropriate and available.

2. Pathology. In South Africa, for example, a network of pathology services already exists. Several specialized, centralized labs are served by a transportation network that connects the remotest clinics to the labs within a timeframe compatible with the tests required. The system will be able to optimize and utilize this network for pathology, as well as for data input. In a novel

approach, the transportation system will also be used to deliver pre-packaged drugs to the clinic to be dispensed by the nurse.

3. Opportunistic infections will be treated.

4. The algorithm will be applied to the patient data, with several possible outcomes:

- Patient's immune system is not compromised enough to require HAART. Patient receives education on the natural history of the disease, nutrition and preventing transmission of HIV. Depending on their nutritional status, supplemental vitamins, minerals, and protein will be dispensed by the system. A novel feature of the system lies in its ability to begin to empower the patient to be compliant with a regular regimen of pills/supplements and follow-up appointments, to have them benefit from support groups, and to keep them within the system so that they receive social and emotional support, and antiretroviral therapy as soon as they require it. These patients will be rechecked according to the intervals outlined in the protocol, for example 3 monthly.

- Patient is severely immune compromised and acutely ill with a severe or life-threatening opportunistic infection. Patient is referred to a hospital or tertiary center, and enters the system on their discharge to their community.

- Patient's immune system is compromised enough to require HAART, but they do not fall within the extremes of the parameters of the system algorithm, or they present with unusual signs and symptoms. The algorithm would refer all cases at the borders of the parameters to be reviewed by a physician, who would enter

orders into the system. Through this mechanism, the parameters of the system would widen to include more variables over time.

- Patient's immune system is compromised enough to require HAART, and they fit comfortably within the parameters of the system algorithm. Patient receives psychosocial support, education on nutrition and preventing transmission of HIV. Depending on their nutritional status, supplemental vitamins, minerals, and protein are dispensed. Patient is educated in the benefits and possible toxicities of HAART, as well as the importance of compliance. HAART and prophylaxis against opportunistic infections per protocol.

- Treatment protocol modified by system algorithm for infants, children, women of child-bearing potential, pregnant and breastfeeding women.

- In all the above the system would incorporate evaluation of associated diseases such as tuberculosis and malaria.

5. Prescriptions. Concurrently, the algorithm will have initiated the dispensing of HAART drugs appropriate to this patient, and they are delivered to the clinic by the transportation system that serves the pathology labs. Prescriptions are pre-packaged and labeled confidentially [i.e. bar coding] for the individual patient, and include culture and education-appropriate instructions. Inherent in the system algorithm is checking for drug interactions, and allergies.

6. Statistical Output. The system algorithm interprets trends both for an individual patient, and within the database as a whole. For example, this allows for detection of conditions such as resistance of HIV to 1st line HAART in an individual or increased incidence of toxicity to a certain drug within an entire area.

The co-occurrence of other diseases and the impact of multiple medicine regimes would also be assessed.

Feedback from cases outside of the parameters of the system algorithm will be considered as the algorithm is constantly updated, so that the parameters of the algorithm become wider and wider. Patient data remains within system, even when they are referred to a different hospital.

7. Communication of data and treatment plans back to nurse. There will be communication back to the nurse regarding patients' status, lab results and treatment/care plan as reflected in the database and interpreted by the algorithm. Communication can be in the form of SMS, or hard copies of reports delivered with the medication. Batch reporting can include such information as upcoming visits, and those who missed appointments and require intervention.

This feedback of processed information to the nurse can be used to empower her by increasing her level of knowledge about the management of HIV and associated diseases, and supporting her in the care of these patients.

8. Patient re-evaluation per protocol. Patients will be re-evaluated according to the protocol. For example, when beginning HAART, patients will be recalled within a shorter duration than those who have proven their compliance and tolerance for the drugs over a period of time. As soon as testing reveals patients' non-compliance, they would be placed on a shorter interval between tests.

THE SYSTEM ALGORITHM

[0045] An algorithm that may be utilized in an illustrative embodiment of the invention is depicted in the flow chart diagram below (Figures 2.1 and 2.2).

Mathematical methodology inherent in the algorithm. The mathematical modeling of the disease management system statistical evaluation center contains many novel and proprietary elements. The process of utilizing

mathematical algorithms developed from statistical and empirical input to forecast outcomes is well known in the art, and is often used in various areas of economic activity, including healthcare. The algorithm based modeling of the system of the present invention, however, is uniquely applied, in an illustrative example, to the treatment of HIV/AIDS patients, together with associated diseases such as TB and malaria. Whereas modeling has typically been used in the past to provide guidance only to professionals, the model of the present invention will provide actual diagnosis of patients, as well as prescription of the applicable medicine regime. The model of the present invention would therefore provide an IT based functionality that enables a lower level healthcare worker to treat patients with a high level of certainty, comparable to experienced HIV/AIDS doctors and specialists.

The model of the present invention is therefore more advanced than known models which merely provide guidance. The model of the present invention, for example, may contain various levels, or parameters, of safeguards to protect patients, and only patients that can be safely treated within a high level of certainty would be directly treated. Patients that fall outside the safe parameters of the model would be referred to an HIV/AIDS specialist. This may occur at a tertiary hospital, by consultation within the algorithm cycle, or in real time via mobile phone, SMS or other appropriate technology. However, all referrals will be monitored by the system, and the outcomes of assessments by specialists would continually be used to upgrade the system model. This enables the system to adjust the safety parameters to treat more patients directly and thereby reducing costs as well as improves the service to patients.

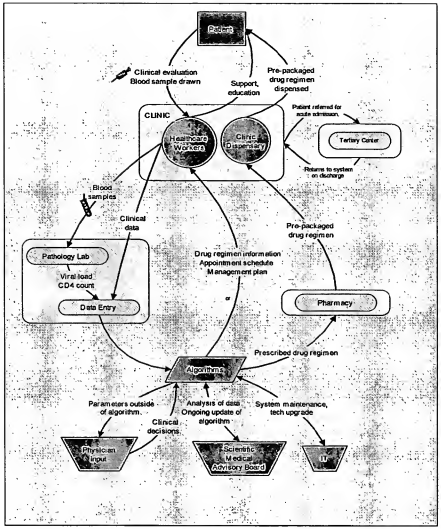
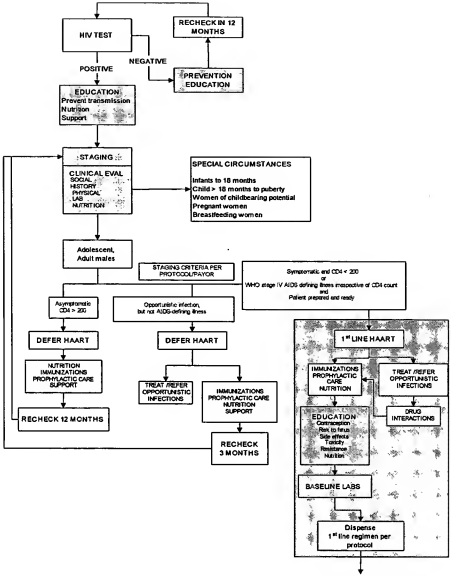

Patient
Clinical evaluation
Blood sample drawn
Support, education
Pre-packaged drug regimen dispensed
CLINIC
Healthcare Workers
Clinic Dispensary
Patient referred for acute stimmson.
Tertiary Center
Returns to system on discharge
Blood samples
Clinical data
Pre-packaged drug regimen
Pathology Lab
Viral load
CD4 count
Data Entry
Drug regimen information
Appointment schedule
Management plan
Pharmacy
Prescribed drug regimen
Algorithm
Parameters outside of algorithm.
Analysis of data
Ongoing update of algorithm
System maintenance, tech upgrade
Clinical decisions
Physician input
Scientific Medical Advisory Board
IT

FIGURE 1



(continues at top of Figure 2.2)

FIGURE 2.1

(continued from bottom of Figure 2.1)

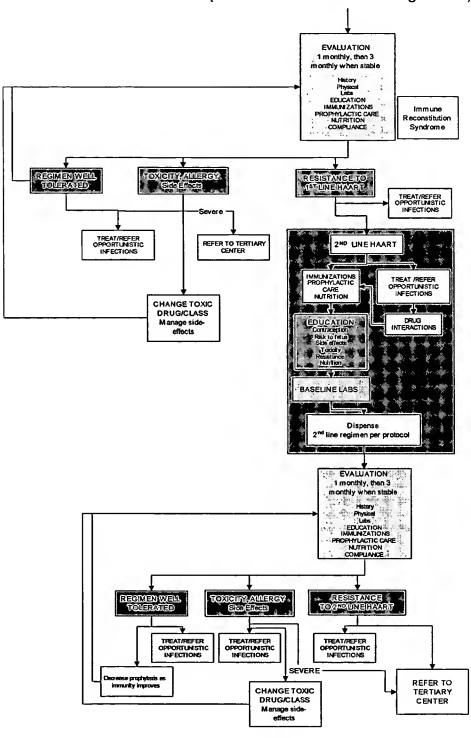


FIGURE 2.2